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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/434,254	11/05/1999	JAMES L. SAY	11554.6USI1	3737

23552 7590 09/11/2003

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EXAMINER
MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
3736	9

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/434,254	Applicant(s) SAY ET AL.	
	Examiner Patricia C. Mallari	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19 and 22* is/are rejected.

7)☒ Claim(s) *18, 20, and 21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 November 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Drawings

This application has been filed with informal drawings, acceptable for examination purposes only. Upon allowance of the application, formal drawings will be required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No.

6,464,849 B1 to Say et al. (herein referred to as the parent case). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-14 of the instant application are merely a broader version of claims 1-14 of the parent case and are covered by claims of the parent case. Claim 1 of the parent case, for example, claims a sensor that comprises a bundle of electrically conductive fibers, a sensing material coating at least some of the fibers in the bundle, and an insulating layer surrounding the bundle of electrically conductive fibers, just as claim 1 of the instant application claims. Claims 2-14 of the instant application, dependent upon claim 1, are similarly covered by claims 2-14 of the parent case.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-8, 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaneko et al. Kaneko teaches a carbon sensor electrode comprising an electrically insulating layer (analyte barrier) 1 or 21, surrounding a plurality of electrically conductive carbon fibers 3 or 23,25 and a sensing material 2 or 24 held inside coating the carbon fibers 3 or 23,25. The carbon fibers are dipped in a hot solution of the reactive substance 2 so as to coat the material 3. The sensor may be a redox type sensor electrode, incorporating an appropriate reactive substance 24, such as iron-EDTA, where iron-EDTA is a transition metal complex with an organic ligand, and using

silicone, for example, as the electrically insulating layer 21. The electrode surface is exposed at a tip portion (figs. 1 & 8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al. in view of Corbett III, et al. Kaneko lacks details as to the insulating layer but teaches a silicone tube in an example corresponding to figure 8. However, Corbett describes a multi-conductor electrical cable wherein each of a plurality of fine wires is coated with an insulating material. The insulating material may be, for example, silicone or polyurethane (col. 3, lines 4-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use polyurethane as the insulating layer in Kaneko since Corbett III, et al. teaches both that polyurethane is an insulating material and that polyurethane and silicone are functionally equivalent.

Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko in view of Gregg et al. Kaneko lacks details as to the active enzyme. However, Gregg describes a biosensor including a redox enzyme, where the enzyme may be glucose oxidase, such that glucose is the analyte being sensed, or lactate oxidase, such that lactate is the analyte being sensed (col. 3, lines 6-52; fig.1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use

lactate oxidase or glucose oxidase as the enzyme in the electrode of Kaneko, since Kaneko teaches using an enzyme, and Gregg teaches that glucose oxidase and lactate oxidase are appropriate enzymes.

Claim 19, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. in view of Kaneko, and further in view of Gregg et al. Douglas describes a lancing device10' having a retractable lancet (blade) 14 that carries a test strip (sensor) 52 near the lancet 14 (fig. 5). Douglas fails to describe the sensor.

However, Kaneko teaches a carbon sensor electrode comprising an electrically insulating layer 1 or 21, surrounding a plurality of electrically conductive carbon fibers 3 or 23,25 and a sensing material 2 or 24 coating the carbon fibers 3 or 23,25. The carbon fibers are coated by reactive substance 2, which may be an active enzyme (figs. 1 & 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the sensor of Kaneko as the sensor of Douglas, since Douglas teaches using a test strip having an electrical circuit, and Kaneko describes such a sensor. Douglas, as modified, is silent as to the active enzyme.

However, Gregg describes a biosensor including a redox enzyme, where the enzyme may be glucose oxidase, such that glucose is the analyte being sensed, or lactate oxidase, such that lactate is the analyte being sensed (col. 3, lines 6-52; fig.1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use lactate oxidase as the enzyme, in the electrode of Douglas, as modified by Kaneko, since Douglas, as modified, teaches using an enzyme, and Gregg teaches that glucose oxidase and lactate oxidase are appropriate enzymes.

Allowable Subject Matter

Claims 18, 20, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,349,229 to Watanabe et al.

US Patent No. 5,777,060 to Van Antwerp

US Patent No. 5,002,651 to Shaw et al.

US Patent No. 4,945,896 to Gade

US Patent No. 4,908,115 to Morita et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Mon-Fri 9:30 am-7:00 pm (alternate Fri. off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

pcm

ROBERT L. NASSER
PRIMARY EXAMINER